

HEALTH AND SENIOR SERVICES

DIVISION OF HEALTH CARE QUALITY AND OVERSIGHT

Manual of Standards for Licensing of Ambulatory Care Facilities

Proposed Amendments: N.J.A.C. 8:43A-2.1, 2.2, 2.4, 2.5 and 16.2

Proposed Repeal and New Rules: N.J.A.C. 8:43A-24

Proposed New Rules: N.J.A.C. 8:43A-32

Authorized by:	<hr/> Fred M. Jacobs, M.D., J.D., Acting Commissioner, Department of Health and Senior Services (with approval of the Health Care Administration Board).
----------------	--

Authority:	N.J.S.A. 26:2H-1 et seq.
------------	--------------------------

Calendar Reference:	See Summary below for explanation of exception to calendar requirement.
---------------------	--

Proposal Number:	PRN 2005-73
------------------	-------------

Submit comments by May 6, 2005 to:

John A. Calabria, Director
Certificate of Need and Acute Care Licensure Program
New Jersey Department of Health and Senior Services
P.O. Box 360
Trenton, New Jersey 08625-0360

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) is proposing to amend N.J.A.C. 8:43A-2.1, 2.4, 2.5 and 16.2, to adopt new rules at N.J.A.C. 8:43A-32 and to repeal and adopt new rules at N.J.A.C. 8:43A-24.

N.J.A.C. 8:43A-2.1 contains outdated text that does not correspond either to statute or Department practice. It requires that ambulatory care facilities seeking to be “instituted constructed, expanded or licensed to operate,” must first apply for and receive a certificate of need issued by the Commissioner. The section provides instructions to apply for a certificate of need and indicates that a facility in receipt of a certificate of need issued by the Commissioner shall “implement all conditions imposed by the Commissioner as specified in the certificate of need approval letter.” Finally, existing N.J.A.C. 8:43A-2.1 states that failure to implement the conditions imposed by the Commissioner, as specified in the certificate of need approval letter, may result in the imposition of sanctions. P.L. 1998, c.43, which amended N.J.S.A. 26:2H-7a, exempts ambulatory care facilities from the certificate of need requirement. Therefore, the Department is taking this opportunity to bring the text of this section in line with statute and practice and is proposing that the entire text of N.J.A.C. 8:43A-2.1 be deleted and that the section be reserved.

The Department is proposing that N.J.A.C. 8:43A-2.2 be amended to eliminate the opening phrase, "Following receipt of a certificate of need or a determination that a certificate of need is not required." As mentioned above, the Department is proposing the elimination of the outdated text pertaining to a certificate of need requirement for ambulatory care facilities that was eliminated in practice in prior years, in accordance with P.L. 1998, c.43. Therefore, the phrase at issue has not been appropriate since enactment of P.L. 1998, c.43. As amended, the first sentence of N.J.A.C. 8:43A-2.2(a) would read, "Any person, organization, or corporation desiring to operate an ambulatory care facility shall make application to the Commissioner for a license on forms prescribed by the Department." Also, the Department is proposing that within the first sentence of N.J.A.C. 8:43A-2.2(l), the introductory phrase "In accordance with N.J.A.C. 8:33-4.10(d)1 through 11," be deleted and the phrase "for licensure under this chapter," be inserted after the words, "All applicants." Thus, the first sentence would read, "All applicants for licensure under this chapter must demonstrate that they have the capacity to operate an ambulatory care facility in accordance with the rules of this chapter." N.J.A.C. 8:33-4.10(d)1 through 11 address requirements for certificate of need applicants. As indicated above, P.L. 1998, c.43, exempts ambulatory care

facilities from the certificate of need requirement. Therefore, the phrase at issue is inappropriate. In addition, the department is proposing that N.J.A.C. 8:43A-2.2(l) be amended so as to make the Department's review of an applicant's prior history in operating a health care facility ("track record evaluation") mandatory, rather than discretionary. Specifically, the Department is proposing that within the third and fourth sentences of N.J.A.C. 8:43A-2.2(l) the word "may" be replaced with the word "shall." In addition, the Department is proposing adding within the final sentence of the subsection a cross-reference to N.J.A.C. 8:43E-5.1, which pertains to track-record evaluation within the context of general licensure procedures. In the licensing process, the Department endeavors to protect the citizens of New Jersey by assuring to the greatest extent possible that a licensed entity provides quality services. The applicant's demonstrated ability to do so (or not) is clearly reflected in its track record. The Department believes that it is important to apply this criterion to all applicants, rather than only to some, since the track record evaluation presages operational difficulties and the ability to comply with licensure requirements.

Finally, the Department is proposing technical amendments to N.J.A.C. 8:43A-2.2 that would reflect changes in contact information, such as address, telephone number and website, as well as changes in organization designation from "Licensing, Certification and Standards" to

“Certificate of Need and Acute Care Licensure” and the “Division of Health Facilities Evaluation and Licensing” to the “Division of Health Care Quality and Oversight.”

The Department is proposing that N.J.A.C. 8:43A-2.4 be amended to reflect that, pursuant to Reorganization Plan No. 004-1996, the then Governor transferred responsibility for construction plan review and construction code enforcement in health care facilities and, therefore, approval of final construction of the physical plant of newly constructed or expanded facilities, from the Department of Health and Senior Services to the Department of Community Affairs. In addition, the Department is proposing technical amendments to N.J.A.C. 8:43A-2.4 and 2.5 that would reflect a change in organizational designation from “Health Facilities Construction Services” and “Health Facilities Inspection Program” to “the Department’s Acute Care Survey Program.”

The Department is proposing that N.J.A.C. 8:43A-16.2(a) be amended to add a new paragraph “14,” which would contain an additional ambulatory care facility patient’s right, namely, the right to expect and receive appropriate assessment, management and treatment of pain as an integral component of that person’s care. This proposed amendment is prompted by P.L. 2000, c.65, which amended N.J.S.A. 26:2H-12.8, adding the above-mentioned right to the list of rights enumerated in the hospital

patient's bill of rights. Although N.J.S.A. 26:2H-12.8 applies to persons admitted to a general hospital licensed under N.J.S.A. 26:2H-1, et seq., the Department has traditionally maintained at N.J.A.C. 8:43A-16.2(a) a list of rights for patients receiving services in an ambulatory care facility that is consistent, where appropriate, with the rights afforded hospital patients. Moreover, due to the increasing complexity of treatment modalities that can be performed on an ambulatory basis, the inclusion of this provision within the rights of patients receiving services in an ambulatory care facility is particularly meaningful. In addition, the Department is proposing that new paragraph "14" contain a cross-reference to N.J.A.C. 8:43E-6, which sets forth the Department's requirements for health care facilities licensed under N.J.S.A. 26:2H-1, et seq., in the area of assessment, monitoring and management of pain. It is the Department's intent in including this cross-reference within proposed N.J.A.C. 8:43A to its pain management standards published elsewhere in the New Jersey Administrative Code, to assist the regulated community in complying with the appropriate standards.

The Department is proposing to repeal and replace the renal dialysis subchapter, codified at N.J.A.C. 8:43A-24, with new rules to update the minimum licensing requirements for the organization, staffing, and patient care services of renal dialysis facilities. The proposed new rules

contained in Subchapter 24 result from advice from a work group, composed both of representatives from the Department and of renal dialysis professionals from New Jersey's health care industry, that was convened several years ago to review and revise licensing standards applicable to both hospitals and ambulatory care facilities for renal dialysis, which have not been substantially revised since 1990. The Department's goal is to update the renal dialysis standards to reflect current clinical standards for renal dialysis services. Additionally, the proposed repeal and new rules are designed to carry out the State Legislature's expressed intent in P.L. 1998, c.43 to rely less on the certificate of need process and more on licensure and inspections of health care facilities to ensure the provision of high quality health care services to New Jersey residents. The proposed repeal and new rules reflect the Department's commitment to protect the public health and safety, pursuant to N.J.S.A. 26:2H-1 et seq., through the rulemaking process. In doing so, the Department is proposing to add training requirements and required qualifications for certain renal dialysis facility staff positions that are not covered under existing N.J.A.C. 8:43A-24. In addition, minimum and maximum dialysis station physical standards have been modified to better conform to financial feasibility and minimum staffing ratio considerations. Minimum and maximum dialysis station size,

for example, is made divisible by three (that is, a proposed maximum size of 21 stations is proposed for an open treatment area compared to the existing standard of 20), to allow for consistency with the minimum adult patient to nurse staffing ratio of three to one (existing N.J.A.C. 8:43A-24.5(a) and proposed at N.J.A.C. 8:43A-24.7). The proposed new rules also reduce the minimum dialysis station size from nine to six, and is based on access considerations, since the proposed smaller minimum size would permit renal dialysis services to meet patient need for renal dialysis in less populated areas of the State. However, a minimally-sized renal dialysis facility would still be required under the proposed rules to meet all other licensing requirements in this chapter. Additional standards are also being proposed to address quality of care issues that have been identified as a result of inspections of existing facilities in recent years. The proposed additional standards result in the creation of separate and more extensive sections concerning dialyzer reuse (proposed N.J.A.C. 8:43A-24.9) and water treatment and dialysate (proposed N.J.A.C. 8:43A-24.10). Within the existing rules both of these areas have been subject only to the provisions governing “infection prevention and control” in existing N.J.A.C. 8:43A-24.6.

The Department’s proposed new rules are summarized as follows:

Proposed N.J.A.C. 8:43A-24.1 sets forth the scope of the licensure requirements for renal dialysis services provided in ambulatory care facilities, including both hemodialysis and peritoneal dialysis services.

Proposed N.J.A.C. 8:43A-24.2 sets forth the definitions of the terms “ambulatory dialysis” and “patient care technician” that are used within this subchapter.

Proposed N.J.A.C. 8:43A-24.3 sets forth a minimum and maximum program size of 6 to 21 stations per treatment area and a provision for establishing [a] transfer agreement(s) with area hospital(s) for inpatient dialysis services or kidney transplantation.

Proposed N.J.A.C. 8:43A-24.4 sets forth the facility’s responsibility to establish policies and procedures for: infection control and prevention; criteria for the acceptance of new patients that include patients with communicable or transmittable diseases; abusive or disruptive patients; orientation of new patients; medical and non-medical emergency procedures; instructing patients and medical staff about emergency procedures; and the prohibition of food in the unit.

Proposed N.J.A.C. 8:43A-24.5 sets forth qualifications of the nephrologists that are required to serve as the renal dialysis program’s medical director. These qualifications are identical to those required by existing N.J.A.C. 8:43A-24.4.

Proposed N.J.A.C. 8:43A-24.6 sets forth renal dialysis staff qualifications, which contain the qualifications for nursing staff and establishes qualifications for the facility's administrator, medical staff, patient care technicians, dietician, and social worker.

Proposed N.J.A.C. 8:43A-24.7 sets forth the requirements for renal dialysis facility staffing including the ratio of registered professional nurses, licensed practical nurses, and trained technicians to patients receiving dialysis treatment, patients receiving home dialysis training, and patients who perform self-care dialysis. The facility's director of nursing is prohibited from serving in this capacity in more than one facility. While the staff to patient ratios for adult patients are identical to those found in the existing rules (at least one trained staff member for every three dialysis patients as set forth at existing N.J.A.C. 8:43A-24.5), the proposed new rules also indicate that the facility's director of nursing may be given patient care assignments, so long as during that time, the director of nursing is physically present in the treatment area and, in addition, is not acting or functioning as the facility administrator. The proposed new section also sets forth the staffing requirements for social workers and dieticians. New staffing requirements for pediatric renal services are included in a proposed new section (N.J.A.C. 8:43A-24.17) and are discussed below.

Proposed N.J.A.C. 8:43A-24.8 sets forth the requirements for infection control and prevention, including those for written policies and procedures that comply with guidelines established by the Centers for Disease Control and Prevention.

Proposed N.J.A.C. 8:43A-24.9 sets forth the requirements for dialyzer reuse that specifically conform to guidelines published by the Association for the Advancement of Medical Instrumentation (AAMI). The proposed new rule also requires facilities to inform patients of the risks of dialyzer reuse, the prohibition on bloodline and transducer reuse, and the need for water analysis to identify endotoxins.

Proposed N.J.A.C. 8:43A-24.10 sets forth the requirements for water treatment and dialysate used in renal dialysis. Specifically, the section sets forth the requirements for insuring that each station is tested semi-annually. In addition, dialysate and water samples are required to be analyzed each month microbiologically with continuous water monitoring, chemical analysis of the water quality, chlorine and chloramine testing. The proposed new rule also sets forth the requirements for written testing records.

Proposed N.J.A.C. 8:43A-24.11 sets forth the requirements for the provision of equipment and supplies for renal dialysis patients, including a

new provision regarding back-up treatment stations to ensure the ready availability of this life-saving service.

Proposed N.J.A.C. 8:43A-24.12 sets forth the requirements for annual staff education and training.

Proposed N.J.A.C. 8:43A-24.13 sets forth the requirement for a patient care plan. Specifically, the section requires a written care plan to be developed within 30 days of initiation of treatment by a multidisciplinary team, discussion of the plan with the patient and/or family, clinical notes, and the transfer of the patient care plan and other pertinent clinical information to a new treatment facility.

Proposed N.J.A.C. 8:43A-24.14 sets forth requirements for clinical records. Specifically, the section establishes requirements for record storage, both paper and electronic, medical history, and laboratory reports.

Proposed N.J.A.C. 8:43A-24.15 sets forth the physical plant requirements for renal dialysis facilities. Specifically, the section sets forth requirements for privacy, handwashing facilities, gross floor space per dialysis unit, handicapped accessibility, equipment storage, and toilet facilities. This section is consistent with the existing rule, which is being repealed as part of this proposal.

Proposed N.J.A.C. 8:43A-24.16 sets forth the requirement for an emergency generator and water supply.

Proposed N.J.A.C. 8:43A-24.17 sets forth the requirements for pediatric dialysis services. Specifically, the section defines a pediatric patient (that is, patients that are less than 14 years old), requires the separation of pediatric patients from adults (except for peritoneal dialysis services), specifies the pediatric equipment that must be used for pediatric patients and specifies the circumstances that require the use of a pediatric nephrologist and pediatric support staff. In addition, there are requirements regarding pediatric nursing qualifications and functions, the pediatric care plan, nurse-patient ratios and infection control requirements specific to the pediatric patient population. The patient to staff ratio for pediatric patients in this proposed section are based on both the age and body weight of the patients receiving dialysis. This proposed new section therefore differs from the existing rule (N.J.A.C. 8:43A-24.5(e)). The existing rule, which is being repealed as part of this proposal, requires two staff to three pediatric patients, with a minimum of one registered nurse present whenever pediatric dialysis services are being provided. The proposed new rule requires a staff to patient ratio of one to one for patients weighing less than 20 kilograms (45 pounds), a staff to patient ratio of two to three for patients weighing from 20 to 40 kilograms (45 to

100 pounds), and a staff to patient ratio of one to three for patients weighing more than 40 kilograms (100 pounds). These proposed staffing ratios for pediatric patients reflect the increasing levels of pediatric patient acuity, the intensity of care required for patients with lower body weights, and the concomitant hemodynamic instability associated with these smaller patients. In addition, specific pediatric physical plant, medical care and infection control requirements are being imposed in this section.

Proposed N.J.A.C. 8:43A-24.18 sets forth the requirements for quality assurance and performance improvement. Specifically, the section sets forth the requirements for the governing body, minimum quality assurance and performance improvement monitoring, and the need for a quality assurance and performance improvement committee.

Proposed N.J.A.C. 8:43A-24.18(c) sets forth the requirement to monitor the quality improvement indicators required by the Trans-Atlantic Renal Council, including the need to monitor the care provided to home dialysis patients. This latter subsection is consistent with the existing rule's requirements (N.J.A.C. 8:43A-24.8), except that the new subsection explicitly indicates some of the Trans-Atlantic Renal Council's quality improvement indicators that are required to be monitored.

Proposed N.J.A.C. 8:43A-24.19 sets forth the requirement for, and responsibilities of, an independent consultant pharmacist.

Proposed N.J.A.C. 8:43A-24.20 sets forth the requirements for home care dialysis services. This section is consistent with the existing rule (N.J.A.C. 8:43A-24.7), which is being repealed as part of this proposal.

Proposed N.J.A.C. 8:43A-24.21 sets forth new requirements for Chronic Kidney Disease (CKD) counseling services, in the event that these services are provided at the facility.

The Department is also proposing new rules in Subchapter 32 regarding the licensure requirements for those services not otherwise addressed in service-specific chapters in N.J.A.C. 8:43A. The new rules proposed at N.J.A.C. 8:43A-32.1 identify the sections of these ambulatory care facility licensing standards (that is, N.J.A.C. 8:43A-1 through 11 and 13 through 19) that are applicable to health care services not addressed by any service-specific licensure criteria in the chapter. The Department is proposing this new section at the request of industry representatives and the Health Care Administration Board. The broad statutory language that defines a “health care facility” and “health care service” (N.J.S.A. 26:2H-2a and 2b) which must be licensed by the Department has resulted in the licensing of a growing range of newer modes of diagnostic and therapeutic services (such as, sleep laboratories, pain management centers, positron emission tomography services, infusion centers) that are

not, at this time, the subject of separate and distinct sections within this chapter. This proposed new section therefore would indicate to potential new health care providers the minimum licensing standards that are to be applicable to any health care service not separately addressed in the chapter.

Proposed N.J.A.C. 8:43A-32.2 includes criteria that would permit the Commissioner to impose additional requirements, beyond those contained in the chapter, in the interest of public safety. It would also permit the Department to incorporate manufacturer's specifications (i.e., applying to physical environment, space, staffing and staff qualifications) in the licensure process, thereby facilitating the licensure of services employing new technology.

Proposed N.J.A.C. 8:43A-32.3 would permit a potential applicant to request waivers for those sections of the chapter's licensing requirements that the applicant believes are not applicable to the health care service(s) proposed for licensure.

As the Department has provided a 60-day comment period for this proposal, this notice is excepted from the calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Health Care Facilities Planning Act and amendments thereto, P. L.1971, c.136 & 138, codified at N.J.S.A. 26:2H-1 et seq., enjoin the Department of Health and Senior Services to protect and promote the public health and safety in New Jersey. The Act mandates the Department to develop “standards and procedures relating to the licensing of health care facilities and the institution of additional health care services” to ensure the continuity and accessibility of health care services.

This purpose is served through the revision of rules for licensure of ambulatory care facilities providing renal dialysis services and other services. The proposed new rules establish minimum licensure requirements for the provision of services by licensed ambulatory care facilities providing renal dialysis services (Subchapter 24) and health care services that are not specifically addressed by the chapter (Subchapter 32).

Establishing rules that set minimum requirements in the operation of ambulatory care facilities is necessary to protect the public health and safety. Facilities must employ qualified staff who possess minimum qualifications to provide services at the appropriate skill level; ensure continuity of care and coordination of services; and provide services that support record keeping and administration of renal dialysis care.

Given the potential benefits to patients accruing from renal dialysis and other health care services, it is important that the facilities providing these services maintain satisfactory quality of patient care. This is especially true in light of the challenges presented to renal dialysis and other health care services by rapid growth in the demand for services and evolving service modalities in an increasingly competitive health care environment. The Department must specify those minimum standards required for safe performance of renal dialysis services in order to continue to protect the consumers of these services. The Department maintains that adoption of these proposed amendments, repeals, and new rules would assure a high level quality of care, leading to improved health, safety and overall wellness of patients receiving renal dialysis and other health care services.

The rule proposal's removal of outdated language referring to certificate of need requirements is not expected to have any social impact, since it reflects changes that were implemented five or more years ago. Likewise, although the requirement to add pain management to the list of patient rights is expected to have a positive social impact, it is likely that the impact will be modest. This is because ambulatory care facilities are already required, in accordance with N.J.A.C. 8:43E, Subchapter 6, to comply with pain management standards for all patients.

Economic Impact

A number of provisions of the proposed amendments, repeals, and new rules would allow greater flexibility in management and administrative practices, such as in developing policies and procedures best suited to their individual facility circumstances; in hiring and allocating staff to best meet patient care needs; and in deciding whether and in what manner to provide services. This would allow facilities to conserve resources by determining the most efficient deployment of their services and personnel.

The rule proposal's removal of outdated language referring to certificate of need requirements is expected to have no economic impact, since it reflects changes that were implemented five or more years ago. Likewise, the proposed addition of pain management to the list of patient rights is also expected to have no economic impact, since all ambulatory care facilities are required, in accordance with N.J.A.C. 8:43E, Subchapter 6, to comply with pain management standards for all patients.

Federal Standards Analysis

The proposed amendments, repeals and new rules do impose standards on licensed ambulatory care facilities, including those providing renal dialysis and other health care services, which exceed federal law or regulation. The applicable Federal standards may be found at 42 C.F.R. §416 for ambulatory care facilities, and at 42 C.F.R. §405.2100, Subpart

V, for end-stage renal disease facilities. The proposed amendments, repeals and new rules contain staffing and training requirements that exceed Federal standards only to the extent that the proposal quantifies and elaborates upon Federal standards that require “appropriate” staffing levels and training, but do not include enough detail to provide suitable licensure criteria. The Department has found it essential to specify minimum standards in greater detail to assure quality. There is no way for the Department to ascertain whether the minimum standards proposed exceed what ambulatory care facilities would provide in any event to meet clinical standards of practice, but if there is increased cost as a result, the concomitant level of quality assurance achieved justifies the increased cost.

Given the potential benefits to patients accruing from renal dialysis and other health care services, it is important that the ambulatory care facilities providing these renal dialysis services maintain safe levels of accessible patient care. This is especially true in light of the challenges presented to renal dialysis and other health care services by rapid growth in the demand for services and evolving service modalities in an increasingly competitive health care environment. The Department maintains that adoption of these proposed amendments, repeals, and new rules would assure a high level quality of care, leading to improved health,

safety and overall wellness of patients receiving renal dialysis and other health care services.

I, Acting Commissioner of the Department of Health and Senior Services, certify that the above statement permits the public to accurately and plainly understand the purposes and expected consequences of the proposed amendment.

Fred M. Jacobs, M.D., J.D.
Acting Commissioner

Jobs Impact

Approval of the proposed amendments, repeals and new rules allow for continued growth in the development of safe and effective ambulatory care services in general, particularly with respect to renal dialysis services. The potential for additional renal dialysis services would necessitate providers recruiting new staff to implement these services in accordance with the staffing requirements established in this section. Thus, promulgation of these rules may have a modest but positive impact on jobs in New Jersey.

Agriculture Industry Impact

The proposed amendments, repeals and new rules would have no impact upon the agriculture industry in New Jersey.

Regulatory Flexibility Statement

The majority of New Jersey's renal dialysis and other health care facilities may be considered small businesses, as the term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14b-15 et seq. These proposed amendments, repeals and new rules to N.J.A.C. 8:43A would update licensure requirements for renal dialysis and other health care providers to ensure quality health care service delivery. Continued compliance with these licensure standards is necessary for all facilities that provide renal dialysis and other health care services in the interest of public health and safety; there should be no differential quality of care standards based solely upon the size of a facility.

Smart Growth Impact

The proposed amendments, repeals and new rules would have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the proposed repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:43A-24.

Full text of the proposed amendments and new rules follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

8:43A-2.1 [Certificate of Need

(a) According to N.J.S.A. 26:2H-1 et seq., and amendments thereto, a health care facility shall not be instituted, constructed, expanded, or licensed to operate except upon application for, and receipt of, a certificate of need issued by the Commissioner.

(b) Application forms for a certificate of need and instructions for completion may be obtained from:

Certificate of Need Program

Division of Health Planning and Resources Development

New Jersey State Department of Health

P.O. Box 360

Trenton, New Jersey 08625-0360

1. Application forms for a certificate of need in the case of a transfer of ownership may be obtained from:

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

P.O. Box 367

Trenton, New Jersey 08625-0367

(c) The facility shall implement all conditions imposed by the Commissioner as specified in the certificate of need approval letter. Failure to implement the conditions may result in the imposition of sanctions in accordance with N.J.S.A. 26:2H-1 et seq., and amendments thereto.] Reserved.

8:43A-2.2 Application for licensure

(a) [Following receipt of a certificate of need or a determination that a certificate of need is not required, a] Any person, organization, or corporation desiring to operate an ambulatory care facility shall make application to the Commissioner for a license on forms prescribed by the Department. Such forms may be obtained from the Department's website address www.state.nj.us/health/hcsa/hcsaforms.html or from:

Director

[Licensing, Certification and Standards

Division of Health Facilities Evaluation and Licensing

P.O. Box 367

Trenton, New Jersey 08625-0367]

Certificate of Need and Acute Care Licensure Program

Division of Health Care Quality and Oversight

P.O. Box 360

Trenton, New Jersey 08625-360

(b) - (k) (No change.)

(l) [In accordance with N.J.A.C. 8:33-4.10(d)1 through 11, a] All applicants for licensure under this chapter must demonstrate that they have the capacity to operate an ambulatory care facility in accordance with the rules of this chapter. An application for a license may be denied if the applicant cannot demonstrate that the premises, equipment, personnel, including principals and management, finances rules and bylaws, and standards of health care are fit and adequate and that there is reasonable assurance that the health care facility will be operated in accordance with the standards required by these rules. The Department [may] shall consider an applicant's prior history in operating a health care facility either in New Jersey or in other states in making this determination for all facilities eligible for licensure under this chapter. Any evidence of licensure violations representing a serious risk of harm to patients[may] shall be considered by the Department, as well as any record of criminal convictions representing a risk of harm to the safety and welfare of

patients pursuant to the enforcement provisions as set forth at N.J.A.C.

8:43E-5.1.

(m) (No change.)

8:43A-2.4 Newly constructed or expanded facilities

(a) (No change)

(b) The licensure application for a newly constructed or expanded facility shall include written approval of final construction of the physical plant by:

[Health Facilities Construction Services

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

PO Box 367

Trenton, New Jersey 08625-0367]

Health Plan Review

Division of Codes and Standards

Department of Community Affairs

PO Box 815

Trenton, New Jersey 08625-0815

Telephone: 609-633-8151

(c) An on-site inspection of the construction of the physical plant shall be made by representatives of [Health Facilities Construction Services] the Department's Acute Care Survey Program to verify that the building has been constructed in accordance with the architectural plans approved by the Department or the Department of Community Affairs.

8:43A-2.5 Surveys and temporary license

(a) When the written application for licensure is approved and the building is ready for occupancy, a survey of the facility by representatives of the [Health Facilities Inspection] Acute Care Survey Program of the Department shall be conducted to determine if the facility complies with the rules in this chapter.

1. (No change.)

2. The facility shall notify the [Health Facilities Inspection] Acute Care Survey Program of the Department when the deficiencies, if any, have been corrected, and the [Health Facilities Inspection] Acute Care Survey Program will schedule one or more resurveys of the facility prior to occupancy.

(b) (No change.)

(c) No facility shall admit patients to the facility until the facility has the written approval and/or license issued by the [Licensing, Certification

and Standards] Certificate of Need and Acute Care Licensure Program of the Department.

(d) - (g) (No change.)

8:43A-16.2 Rights of each patient

(a) Each patient receiving services in an ambulatory care facility shall have the following rights:

1. through 13. (No change.)

14. To expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care in accordance with N.J.A.C. 8:43E-6.

SUBCHAPTER 24. RENAL DIALYSIS

8:43A-24.1 Scope of renal dialysis standards

The standards within this subchapter shall apply to both hemodialysis and peritoneal dialysis units within ambulatory care facilities providing renal dialysis services. Ambulatory care facilities that provide chronic dialysis services shall comply with N.J.A.C. 8:43A-1 through 11 and 13 through 19, and this subchapter. Hospital facilities that provide renal dialysis services within the hospital shall comply with N.J.A.C.

8:43G-30 and with the requirements of this subchapter, except as specifically modified by N.J.A.C. 8:43G-30.

8:43A-24.2 Definitions

The following terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

“Ambulatory dialysis” means maintenance dialysis therapy provided to an individual on an outpatient basis.

“Patient care technician” means unlicensed dialysis facility staff who has been specifically trained and demonstrates competency to provide direct patient care, under the direct supervision of a registered professional nurse, to individuals receiving dialysis services.

8:43A-24.3 Minimum program size and transfer agreements

(a) A facility providing ambulatory dialysis services shall have at least six stations. In the case of new construction or renovation involving at least 25 percent of the existing physical plant, an open treatment area shall contain no more than 21 stations.

(b) A facility providing ambulatory dialysis services shall have a written transfer agreement with at least one hospital with a New Jersey license to provide inpatient dialysis and with at least one hospital having a

Medicare-certified and Department-licensed renal transplantation program.

8:43A-24.4 Renal dialysis policies and procedures

(a) The renal dialysis service shall have written policies and procedures that are reviewed every three years, revised as needed, and implemented. They shall include at least:

1. Admission criteria for the ambulatory dialysis service that includes acceptance of patients who have communicable or transmittable diseases.

2. Criteria for handling the abusive or disruptive patient;

3. Orientation of new patients to the unit;

4. Specific facility response to medical and non-medical emergencies including, for example, equipment failure and water supply problems; and

5. Prohibition against patients bringing food into the unit, except for beverages which may be allowed at the discretion of the facility director.

(b) The renal dialysis service shall have written infection control policies and procedures specific to the renal dialysis unit that include standard industry precautions. The written policies and procedures shall

be in accordance with the current edition of the Centers for Disease Control and Prevention (CDC) publication "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, MMWR, Vol. 50, No. RR-5, April 27, 2001, as amended and supplemented, available from the CDC, Atlanta, Georgia, 30333, incorporated herein by reference.

8:43A-24.5 Qualification of the medical director

_____ The medical director of a facility that provides ambulatory dialysis services shall be a nephrologist. A medical director designated prior to July 1, 1993, shall have the qualifications of a nephrologist as specified at N.J.A.C. 8:43A-1.15. A medical director designated on or after July 1, 1993, shall be certified in the subspecialty of nephrology by either the American Board of Internal Medicine or the American Board of Medical Specialties or by the American Osteopathic Board of Internal Medicine, Bureau of Osteopathic Specialists of the American Osteopathic Association.

8:43A-24.6 Renal dialysis staff qualifications and policies and procedures

(a) Renal dialysis services shall be under the administrative supervision of an individual with at least one of the following qualifications:

1. A baccalaureate degree from an accredited college or university and the equivalent of at least one year experience in supervising renal dialysis services; or

2. Five years full-time experience in the provision of renal dialysis services and documentation of supervisory experience for at least one year.

(b) The medical staff shall possess the following qualifications:

1. Each physician on the medical staff shall have a current license to practice medicine in the State of New Jersey, and current Drug Enforcement Administration (DEA) and Controlled Dangerous Substances (CDS) certificates.

2. The members of the medical staff may include nephrologists and other physicians with training or demonstrated experience in the care of end stage renal disease patients.

3. Advanced practice nurses or physician assistants shall meet the requirements established by the Board of Nursing in New Jersey (for an advanced practice nurse – N.J.A.C. 13:37-7) or the Board of Medical Examiners in New Jersey (for a physician assistant – N.J.A.C. 13:35-2B).

(c) The director of nursing services is the registered professional nurse who has overall responsibility for the provision of nursing care in the facility. The director of nursing shall have a current New Jersey license to

practice nursing and shall meet the qualifications set forth in N.J.A.C. 8:43A-1.10, except that the minimum 12 months of full-time experience in nursing supervision and/or nursing administration shall have been obtained in a hemodialysis setting within the last 24 months.

(d) Each nurse assigned charge responsibilities shall be a New Jersey-registered nurse currently licensed to practice and have 12 months of full-time experience in hemodialysis obtained within the last 24 months. The responsibilities of a registered professional nurse functioning as a charge nurse shall include:

1. Making daily patient care assignments based on patient needs;
2. Providing immediate supervision of direct patient care;
3. Making patient assessments when indicated; and
4. Communicating with the other members of the health care team.

(e) Dialysis facilities shall assign licensed practical nurses to perform nursing functions within their defined scope of practice, as set forth in the New Jersey Nurse Practice Act at N.J.S.A. 45:11-23.

(f) Patient care technicians shall be subject to the following policies and procedures:

1. Technicians shall be trained and deemed competent by the facility in accordance with facility policies and procedures in the following areas:

- i. Principles of hemodialysis;
- ii. Understanding the individual with kidney failure;
- iii. Application of dialysis procedures;
- iv. Application of dialysate, dialysers and reuse;
- v. Water treatment.

2. A competency evaluation covering the areas identified in (f)1 above shall be performed for each patient care technician and shall be included as a component of the policies and procedures.

i. Until the successful completion of each component of the competency evaluation, the trainee may provide patient care only as part of the training program and under the direct supervision of an assigned preceptor. A preceptor shall be a licensed registered nurse who has 12 months of experience in hemodialysis obtained within the last 24 months and a recommendation by the supervising nurse to be a preceptor.

ii. An individual may not work as a patient care technician unless and until that individual has satisfied the competency requirements in each of the five training areas established in (f)1 above.

3. Trainees shall be identified as such to patients in the treatment area. Trainees shall not be included in the determination of compliance with minimum staffing ratios as set forth at N.J.A.C. 8:43A-24.7(a).

4. Patient care technicians are prohibited from performing any of the following activities:

- i. Comprehensive clinical assessment of the patient;
- ii. Primary responsibility for patient education;
- iii. Alteration of ordered treatment, including shortening of the treatment time.
- iv. Administration of medications;
- v. Administration of blood or blood products;
- vi. Performance of non-access site arterial puncture; or
- vii. Acceptance of physician orders.

(g) Registered dietitians shall possess at least one year of clinical experience as a registered dietitian.

(h) Social workers shall possess a master's degree in social work from a program accredited by the Council on Social Work Education. The facility shall designate one social worker in charge of social services.

8:43A-24.7 Dialysis staffing

(a) The qualified individual who serves as the director of nursing services, as defined in N.J.A.C. 8:43A-8.2, shall have that responsibility at only one facility.

(b) The director of nursing services may also function as facility administrator or alternate facility administrator.

1. However, if the director of nursing is functioning in an administrative capacity, this individual shall not assume patient care and/or charge nurse responsibilities.

2. In addition, under no circumstances shall any direct care personnel, including the charge nurse, perform any administrative responsibilities for the facility.

(c) At least one registered nurse shall be on duty for the first nine patients receiving dialysis services on the premises and an additional registered nurse shall be on duty for each additional nine patients, or any portion thereof.

(d) At least one registered nurse, licensed practical nurse, or trained patient care technician shall be on duty for every three patients receiving dialysis services.

(e) All registered nursing staff shall receive on-site training in renal dialysis techniques, as determined by the facility, before permitted to work independent of direct supervision of another registered nurse with 12 months experience in hemodialysis nursing.

(f) Only a registered nurse shall direct the home (self) care dialysis training program.

1. The registered nurse may elect to assign home (self) care training licensed practical nurses.

2. One licensed nurse shall be on duty for every two patients on the premises receiving home (self) care dialysis training.

(g) If self-care dialysis services are provided on the premises, there shall be a minimum of one licensed nurse on duty for every six patients on the premises receiving self-care dialysis, exclusive of personnel engaged in training.

8:43A-24.8 Infection prevention and control

(a) The administrator shall designate a person with training or experience in surveillance, prevention, and control of nosocomial infection who shall be responsible for the direction, provision, and quality of infection prevention and control services.

(b) The facility shall have written infection control policies and procedures specific to the dialysis service, which shall include standard precautions in accordance with N.J.A.C. 8:43A-24.4(b).

(c) Transducer filters shall be replaced if wetted.

(d) The facility shall maintain dialysis infection control standards as recommended in the current guidelines from:

Centers for Disease Control and Prevention

1600 Clifton Road

Atlanta, GA 30333.

8:43A-24.9 Reuse of dialyzers

(a) If dialyzers are reused, reuse shall conform with guidelines in the Association for the Advancement of Medical Instrumentation (AAMI) publications, "Recommended Practice for Reuse of Hemodialyzers," incorporated herein by reference as amended and supplemented.

Note: AAMI publication can be obtained from:

Association for the Advancement of Medical Instrumentation

Suite 602

1901 North Fort Meyer Drive

Arlington, VA 22209

(b) The facility's policy on dialyzer reuse shall be explained to all renal dialysis patients.

1. Patients who consent to reuse shall sign an informed consent form informing them of the risks associated with dialyzer reuse.

2. If the patient declines reuse, arrangements shall be made for the patient to receive single-use treatment in the unit.

(c) Reuse of bloodlines and transducer filters is prohibited.

(d) Water used in dialyzer reprocessing systems shall be analyzed for endotoxins from the water source outlets at least monthly and more often as necessary.

(e) In the case of centralized reuse processing, the facility is responsible for the quality of the reuse dialyzer and performance standards.

8:43A-24.10 Water treatment and dialysate

(a) Water treatment equipment, water, and dialysate shall satisfy the requirements specified in the Association for the Advancement of Medical Instrumentation (AAMI) publication entitled "American National Standard for Hemodialysis Systems," as amended and supplemented, incorporated herein by reference.

1. Samples shall be taken at the first and last station and at least 10 percent of the stations on a rotating basis within the distribution system to insure each station is tested semi-annually. A calibrated loop may not be used in microbiological testing of water samples.

2. Water and dialysate samples shall be microbiologically analyzed at least monthly. Water samples shall be taken immediately beyond the last water treatment device and at other locations in each treatment area so as to ensure that water throughout the distribution lines conforms with AAMI standards.

i. The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms which can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect the quality of the product water as measured by this device shall be located after the sensing cell.

ii. Chemical analysis of the water shall be performed every six months and following any change in the water system which may cause a degradation of the water quality.

3. The chlorine and chloramine testing shall be done at the start of daily operations and at times no greater than six-hour intervals daily.

4. Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series appropriately used.

5. Preparation of dialysate onsite requires the facility to establish policies and procedures to assure the safety and efficacy of the dialysate solution. A record of preparation of the dialysate shall be maintained.

6. Water supply systems shall be designed to supply water to the fixtures and equipment at a minimum pressure recommended by the manufacturer during periods when fixtures and equipment are in use.

7. The facility shall have written policies outlining the training, responsibilities, and competencies of staff responsible for maintaining water treatment processing.

8. Written records of analysis procedures and results and of equipment maintenance shall be maintained in the facility daily. Written records of daily analysis procedure results shall be maintained. Daily logs shall include the acceptable parameters for the processes being monitored.

9. Each facility shall maintain records documenting staff responsible for water procedures and monitoring.

8:43A-24.11 Supplies and equipment

(a) Every facility shall have at least one operational back up machine for the first six machines. For each additional ten machines, an additional operational back up machine is required.

(b) All equipment that is present in the facility shall be functional and maintained in operational condition and in sufficient numbers to adequately service all patients.

(c) The facility shall follow all procedures and processes as required or recommended by the manufacturer of the dialysis equipment being used in the treatment of patients.

(d) Patients shall be dialyzed in chairs that can be adjusted so that the patient's head is lower than his or her feet, except when the patient is dialyzed in a hospital bed or stretcher.

8:43A-24.12 Renal dialysis staff education and training

(a) Each facility shall develop, revise as necessary, and implement a written plan of staff education. The plan shall address the educational needs, relevant to the renal dialysis service, of different categories of staff on all work shifts. The plan shall include education programs conducted at least annually.

(b) The staff education plan shall include education programs that address at least the following:

1. Orientation of all staff to the facility or service in which the individual will be employed including a review of the service's equipment,

policies, and procedures and identification of individual employee duties for receiving and evacuating patients in the event of a disaster;

2. Use of new clinical procedures, new equipment, and new technologies, including where applicable, computers;

3. Individual staff requests for education programs;

4. Educational needs based on assessment of staff performance and competency;

5. Facilities shall establish a process for evaluation of staff competencies, which shall be performed and documented at least annually;

6. Areas identified by the facility quality assurance program as needing additional educational programs; and

7. Rights and responsibilities of staff under the New Jersey Advance Directives for Health Care Act (N.J.S.A. 26:2H-53) and the Federal Patient Self Determination Act (42 USCS § 1395cc(f)) and internal facility policies and procedures to implement these laws.

(c) Facilities shall maintain a record of attendance for each educational program offered and composite records of inservice participation for each staff member.

8:43A-24.13 Patient care plan

(a) The referring or transferring facility shall provide the receiving facility the most recent patient care plan, copies of summaries of the patient's treatments, records, medical progress, a description of dietary care, a summary of the patient's current needs and results of laboratory tests prior to transfer.

(b) Within one calendar month of initiation of dialysis treatment at the facility and annually thereafter, a written plan of care shall be developed and designated as the patient's long term treatment plan. The multidisciplinary team shall analyze patient outcomes on a regular basis to assess the patient's progress and evaluate current and future treatment modalities and modify the plan as necessary.

(c) Within one calendar month of initiation of dialysis treatment at the facility, a written plan of care shall be developed for each ambulatory dialysis patient by a multidisciplinary team consisting of at least, a nephrologist, a transplant surgeon or designee, a registered professional nurse, a dietitian, and a licensed social worker. The plan of care shall specify observable and measurable goals and expected patient outcomes.

(d) Every six months at minimum, the multidisciplinary team shall discuss and review the written patient care plan with each ambulatory dialysis patient and/or family, and shall revise as needed.

(e) Each member of the multidisciplinary team shall enter progress notes into the chronic dialysis patient's medical record. Progress notes by the physician, registered professional nurse and dietician shall be entered in the patient's medical record at least monthly and by the social worker at least quarterly.

8:43A-24.14 Medical records

(a) In addition to compliance with the requirements of N.J.A.C. 8:43A-13.1 et seq., the facility shall assure the following:

1. An area for medical records storage, which is separate from all patient treatment areas, shall be provided. The medical records area shall have adequate space for reviewing, dictating, sorting, or recording records. If electronic imaging devices are employed (that is, microfilm or optical disc), the medical records area shall have adequate space for transcribing records in electronic format. The facility shall store the active medical record of each patient currently treated by the facility on site.

2. Signature stamps are not used to authenticate medical record entries.

3. Each medical record shall include: _____

i. Problem list, including access surgeries for dialysis and prior hospitalizations;

ii. Transfusion record;

iii. Record of creation and revision of access for dialysis;

iv. Evidence of patient education;

4. A patient's medical history and physical examination shall be completed within 30 days before or two weeks after initial treatment at the facility. For physical examinations performed prior to admission to the renal facility, the admitting physician, nurse practitioner, or physician assistant shall review the physical examination findings prior to the patient's first treatment at the renal dialysis facility and shall indicate on the physical exam form any significant changes in the patient's medical condition that occurred since the physical examination was performed.

i. Prior to the first treatment in the facility, the physician shall inform the nurse functioning in the charge role of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. The clinical record shall include this data. No dialysis shall be initiated until this requirement is met.

5. Prior to providing dialysis treatment of a transient patient, a facility shall obtain and include, at a minimum:

i. Orders for treatment in the facility;

ii. A list of the patient's current medications and any known patient allergies;

iii. Laboratory reports performed no later than one month prior to treatment at the facility, including screening for hepatitis B status;

iv. The most current patient care plan; and

v. The most current treatment records from the referring facility.

6. At the completion of treatment at the transient facility, records of care and treatment are provided to the referring facility.

8:43A-24.15 Physical plant requirements for all ambulatory dialysis facilities

(a) Each station in the ambulatory dialysis service shall have a curtain for privacy. One handwashing sink shall be available for every four stations. These handwashing sinks shall be distributed throughout the treatment area so as to ensure immediate accessibility to staff at all times.

(b) The minimum dimensional requirements for each dialysis station shall be:

1. There shall be a minimum width of 10 feet along the service wall.

2. The floor area within the cubicle curtain of each dialysis station shall be at least 80 square feet and shall not include the area of the service wall.

3. There shall be 30 inches of clear space around each machine and lounge, except that one side of the machine may be installed flush against the wall.

4. There shall be a minimum of four feet between beds and/or lounges.

5. The dimensional requirements listed in (b) 1 through (b)4 above shall apply to those facilities initially licensed six months or later from the effective date of these rules.

6. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided in (b)1 through (b)4 above.

(c) The floor of the dialysis treatment area, reuse rooms, soiled utility rooms, and any areas used for mixture of dialysate shall be monolithic with integral base.

(d) There shall be a separate clean holding area or room within the ambulatory dialysis suite for storage of clean supplies.

1. If the facility has a clean utility room, then the clean utility room shall contain a minimum of 120 square feet and handwashing facilities.

i. This dimensional requirement shall apply to those facilities licensed six months from the effective date of these rules.

ii. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided in this section.

(e) There shall be a separate soiled utility room within the ambulatory dialysis suite.

1. The soiled utility room shall contain a minimum of 120 square feet and shall contain a sink equipped for handwashing.

i. This dimensional requirement shall apply to those facilities licensed six months from the effective date of these rules.

ii. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided in this section.

(f) A separate janitors' closet shall be provided exclusively for the ambulatory dialysis suite.

1. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(g) A separate, handicapped accessible toilet room with handwashing facilities shall be provided for patients.

1. Each 21 station increment requires a minimum of one handicapped-accessible toilet to be provided.

2. Toilet room locations shall be distributed throughout the treatment area for patient access.

(h) A staff breakroom/lounge/locker room shall contain a sink, a workcounter, a refrigerator, storage cabinets and equipment for serving nourishments, as clinically required by the patient.

1. Toilet facilities with handwashing facilities shall also be provided.

2. The breakroom/lounge/locker room shall be sized in accordance with the anticipated amount of employees.

(i) The nurses' station shall be designed and located so as to permit visual observation of each patient station.

(j) Door(s) to patients' toilet room(s) shall be equipped with hardware which permits access from the exterior by staff in any emergency.

(k) If home training rooms are provided, each room shall be equipped with a sink for handwashing.

(l) If chronic kidney disease counseling (CKD) services are provided, the facility shall provide space for the provision of CKD

counseling services which affords patient privacy and which is separate from the hemodialysis treatment area(s).

(m) Storage space shall be provided for wheelchairs and stretchers out of the direct line of traffic to permit unobstructed egress.

(n) A room shall be provided for storage of equipment used in the patient care area.

(o) An examination room shall be provided with a minimum of 80 square feet of clear floor area exclusive of the work counter and lavatory for handwashing.

1. Facilities licensed within six months of the effective date of these rules shall not be subject to the dimensional requirements of this provision.

2. In the case of new construction or renovation involving at least 25 percent of the physical plant, ambulatory renal dialysis units shall be required to conform to the standards provided herein.

(p) Office space shall be provided for administration, medical and nursing services, social work services, and dietary counseling services.

(q) Space for conferences, consultation, and other purposes shall be provided.

(r) A waiting area with access to a telephone, toilet facilities, and a drinking fountain shall be provided.

(s) Each toilet facility for patients shall be served by an emergency call system. Calls shall activate a signal at the nurses' station.

(t) There shall be a medication administration station for the ambulatory dialysis service.

1. The medication administration station shall contain handwashing facilities, a work counter, a refrigerator, and locked storage for biologicals, medications, and syringes.

i. Provisions shall be made for the controlled storage, preparation, and administration of medications.

2. Each 21-station increment requires a minimum of one drug distribution station.

i. The distribution stations shall be interspersed throughout the treatment area for easy staff access.

(u) Patient records shall be kept in a secure area.

8:43A-24.16 Emergency generator and water supply

(a) An emergency generator shall be provided in a room which shall have a one-hour fire rating with an approved fresh air intake and an explosion release. All machines shall be connected to the emergency generator so that all machines will operate for at least four hours following a power shutdown or outage.

8:43A-24.17 Requirements for pediatric dialysis services

(a) The physical plant requirements for pediatric dialysis services shall be established as follows:

1. If pediatric dialysis services are provided, they shall be located in a treatment area separate from the services provided to adults except if peritoneal dialysis is the service in which case, training and back-up care may be integrated into an adult unit. Pediatric patients are defined as patients who are less than fourteen (14) years of age.

2. The area housing the pediatric dialysis unit shall be enclosed with fixed partitions that extend from finished floor to ceiling. Vision panels in partitions are required.

3. The pediatric dialysis unit shall have handwashing facilities that are separate from the adult unit.

4. If pediatric patients are treated, the facility shall use equipment, supplies, and emergency devices to include blood pressure cuffs, dialyzers, and bloodlines approved for use on pediatric patients.

(b) All patients admitted to the facility under the age of 18 for renal dialysis services shall be evaluated by a pediatric nephrologist. Any patient 13 years old or under shall be under the care of a pediatric nephrologist at all times. After the initial evaluation and at the discretion of

the pediatric nephrologist, the treatment of patients 14 -18 years old may be referred to nephrologists who specialize in the care of adult dialysis patients.

(c) The requirements for nursing care shall be established as follows:

1. The facility shall maintain documentation of competencies in general pediatrics and/or pediatric nephrology for all licensed professional nurses responsible for providing care to a pediatric renal patient. Such individuals shall demonstrate current competencies in pediatric care.

2. Patients age 13 and under must be dialyzed by a registered nurse.

3. Patients over the age of 13 and whose weight is greater than 30 kilograms may be dialyzed by a licensed practical nurse or patient care technician only after a registered nurse has assessed this patient and only under the supervision of a registered nurse.

4. All patient assessments are the responsibility of the registered nurse.

5. Nurse-patient ratios shall be established as follows :

i. For patients whose weight is less than 20 kilograms, the nurse patient ratio shall be 1 to 1;

ii. For patients whose weight is 20 to 40 kilograms, the nurse-patient ratio shall be 1 to 2;

iii. For patients whose weight is greater than 40 kilograms, the nurse-patient ratio shall be 1 to 3.

(d) The pediatric care plan shall be established as follows:

1. The pediatric care plan shall be developed by a multidisciplinary team as set forth in N.J.A.C. 8:43G-30.12.

i. The pediatric patient care plan shall address those issues specific to but not limited to growth and development, nutrition, and patient and family education.

ii. All pediatric renal patients shall be seen and evaluated by a transplantation team within 90 days of admission.

(e) The requirements for infection control practices and procedures shall be established as follows:

1. Patients shall receive all age appropriate immunizations with documentation noted in the record. If immunizations are not administered, the reasons must be documented.

2. Varicella vaccine shall be administered to all patients under the age of 12 months who have not had documented varicella infection or documented Varicella antibody titer.

8:43A-24.18 Renal dialysis quality assurance plan

(a) In addition to the requirements set forth in N.J.A.C. 8:43A-18, the facility shall develop a quality assurance plan that includes all areas of service, management and operations, which shall be monitored by the governing body.

(b) The governing body is responsible for the following:

1. Establishment of program goals and objectives;
2. Oversight of program implementation, revision and effectiveness;
3. Allocation of sufficient time and resources to accomplish objectives and attain goals;
4. Inclusion of all attending physicians and other categorical key personnel in program operation; and
5. Quality assurance activities shall demonstrate that facility staff evaluate the provision of dialysis care and patient services, set treatment goals, identify opportunities for improvement, develop and implement improvement plans, and evaluate implementation until resolution is achieved.

(c) At a minimum, the quality assurance plan shall analyze those indicators required by the Trans-Atlantic Renal Council (180 Tices Lane,

East Brunswick, New Jersey 08816). These include indicators to monitor the following:

1. Infection control measures, for example, standard precautions and machine cultures;
2. Hemodialyzer processing;
3. Water quality;
4. Physical environment for maintenance and housekeeping issues; and
5. Transplantation referrals;
6. Home dialysis.

(d) Meetings of the quality assurance and performance improvement committee shall be held at least quarterly and shall be separate from other patient care or management meetings. Written minutes of each meeting shall be maintained; these minutes shall include a formal agenda, attendance record, items considered, action decided and review of actions implemented. Minutes and other material considered during the meeting shall be kept on file, provided to the governing body in a timely manner, and readily available for at least the previous seven quarters.

8:43A-24.19 Consultant Pharmacist

(a) The facility shall retain a consultant pharmacist who has no affiliation with the pharmacy that provides services to the facility, the facility in which services are provided, or any of their affiliates. The consultant pharmacists' responsibilities shall include, but not be limited to:

1. Responsibility for the direction, provision and quality of pharmaceutical services;

2. Development and/or review of all facility policies and procedures regarding pharmaceutical services. Policies and procedures shall include the development and maintenance of written objectives, an organizational plan and continuous quality improvement regarding the administration, storage, control and disposition of medications at the facility;

3. Offering educational programs in pharmacology to facility staff at the request of the facility administrator, director of nursing, or as required by the use of new medication systems, pharmacological innovations or advances in technology;

4. Conduct individual drug regimen reviews and provide pertinent information related, but not limited to, potential adverse reactions, drug interactions, medication dosage, pharmacokinetics, pharmacodynamics, pharmacoeconomics, at the request of the facility administrator.

5. At minimum, conduct quarterly reviews of medical records and all areas in the facility in which medications are dispensed, administered, stored, or destroyed, document any problems, and propose solutions to problems.

6. The consultant pharmacist shall submit written reports, at least quarterly, to the administrator and the medical director.

8:43A-24.20 Home care dialysis services

(a) If home (self) care dialysis services are provided, the facility shall establish, implement, and review, at least annually, written policies and procedures including, but not limited to, policies and procedures for the following:

1. Development of a written outline of the home (self) care training program, including didactic and practical sessions, for the unsupervised performance of dialysis treatments by patients and family;

2. Home visitation program, in which a registered professional nurse assesses the physical environment of the home, the patient's ability to perform home dialysis treatments, and the level of support that is available to the patient from family members or significant others;

3. Availability of teaching materials for patient use during and after home (self) care dialysis training and at times other than during the dialysis procedure;

4. Provision of consultation to the patient by a social worker and a dietitian;

5. Installation and maintenance of equipment in the home;

6. Testing and treatment of the water in the home; and

7. Ordering of supplies for the home on an ongoing basis.

8:43A-24.21 Chronic Kidney Disease Counseling Services

(a) If chronic kidney disease (CKD) counseling services are provided, the facility shall establish, implement and review, at least every three years, written policies and procedures which shall include at least the following:

1. Development of a patient educational program which shall include, but is not limited to, the following:

i. Prevention/treatment of complications of CKD (i.e., hypertension, anemia, malnutrition, bone disease).

ii. Treatment of cardiovascular disease and diabetes.

iii. Renal replacement therapy options (i.e., hemodialysis, peritoneal dialysis, transplantation).

iv. Improvement of personal health (i.e., diet and exercise).

v. Preparation for dialysis (i.e., arm preservation, vascular access planning).

2. Delineation of the teaching/educational materials which shall be distributed to the patient.

3. Documentation in the medical record of the type, content and frequency of the CKD services provided.

4. Policies and procedures for laboratory, medication administration and/or treatment services, if provided.

(b) A registered professional nurse shall direct the CKD counseling services and shall be present at the facility during the time such services are provided to patients.

(c) The facility shall ensure that evaluation and counseling services are provided by a multidisciplinary team, which shall include a nephrologist, a registered professional nurse, a dietitian, and a social worker.

(d) The multidisciplinary team shall develop an individualized plan of care for CKD counseling services and any related health care services provided.

SUBCHAPTER 32. OTHER SERVICES

8:43A-32.1 General provisions

The following standards shall apply to health care services not specifically addressed in these rules. All ambulatory care facilities shall comply with N.J.A.C. 8:43A-1 - 11 and 13 - 19.

8:43A-32.2 Services Not Described in these Rules

(a) In the case of a licensing application for a health care service for which the Department has no specific licensing standards, the Commissioner may impose additional requirements beyond the requirements contained in these rules, in order to protect the health of the inhabitants of the State.

(b) If a licensing applicant proposes to utilize a new technology for which the Department has no specific licensing standards, then the applicant shall provide the Department with manufacturer's specifications for the equipment or technology proposed and documentation of compliance with these specifications.

8:43A-32.3 Waiver Requests

If a licensing applicant believes that certain existing requirements of N.J.A.C. 8:43A do not apply to the service proposed, then the applicant may request a waiver from those specific standards. Such requests shall follow the process outlined at N.J.A.C. 8:43A-2.9. Waiver forms are available at the Department's website address www.state.nj.us/health/hcsa/hcsaforms.html or from:

Director

Certificate of Need and Acute Care Licensure Program

Division of Health Care Quality and Oversight

New Jersey State Department of Health and Senior Services

P.O. Box 360

Trenton, New Jersey 08625-0360